

K022086 Page 1 of 2



DEC 23 2002

Invitrogen Corporation
3175 Staley Road
Grand Island, New York 14072
P: 716 774 6700

510(k) Summary
Invitrogen Corporation AIM-V® Medium

Device Name: AIM-V® Medium

Common/Usual Name: AIM-V

Classification Name: Tissue culture media for human *ex vivo* tissue and cell culture processing applications (per 21 CFR § 876.5885)

Product Code: NDS

Submitter: Invitrogen Corporation
3175 Staley Road
Grand Island, New York 14072

Telephone: (716) 774-6713

Facsimile: (716) 774-6996

Contact: Keith Gittermann

Date Prepared: June 26, 2002

Predicate Device:

<u>Trade Name</u>	<u>Manufacturer</u>	<u>510(k)</u>
Dulbecco's Modified Eagle Medium	Invitrogen Corporation (formerly Life Technologies, Inc.)	K001447

Intended Use

AIM-V® Medium is a liquid tissue culture media product intended for human *ex vivo* tissue and cell culture processing applications.

Substantial Equivalence

Dulbecco's Modified Eagle Medium (DMEM) is the predicate device for tissue culture media intended for human *ex vivo* tissue and cell culture processing applications. It is composed of chemically defined nutrient materials in solution (with or without supplements) that are essential for the survival and development of tissue or cells of human or other animal origin. These nutrients are provided in liquid form for use in supporting the growth or maintenance of human tissue and cells.

A. Intended Uses

AIM-V® Medium and DMEM tissue culture products are intended for human *ex vivo* tissue and cell culture processing applications. Both devices are chemically defined tissue culture media used to support the growth or maintenance of human tissue or cells in culture.

B. Principles of Operation and Technological Characteristics

AIM-V® is a serum-free medium developed in 1987 to support adoptive immunotherapy (lymphokine-activated killer (LAK) cells) clinical trials being conducted by Dr Steven Rosenberg (National Cancer Institute) and collaborating investigators. Many of the applications of AIM-V® are at the clinical investigation stage, although some procedures have been approved by the appropriate regulatory agency. In addition, the medium has been found to be useful in a growing list of applications, including culturing functionally differentiated lymphoid cell lines, investigating signal transduction pathways, and performing applications requiring component definition. The general use of tissue culture media products for human *ex vivo* tissue and cell culture processing applications has been extensively described in peer-reviewed literature.

The formula for AIM-V® has remained the same since it was first manufactured with only slight quantity variations. AIM-V® Medium is prepared from a master formulation of Dulbecco's Modified Eagle Medium, HEPES buffer, human serum albumin, USP, human transferrin, and cholesterol, NF (which help promote growth of the cells and tissue).

C. Conclusion

AIM-V® and Dulbecco's Modified Eagle Medium are used for human *ex vivo* tissue and cell culture processing applications and have the same principles of operation, technological characteristics, efficacy (generic cellular growth and maintenance) and safety (consistency in chemical content and formulation, biocompatibility with cells, and purity). Their efficacy in supporting the survival, growth, development, and maintenance of human cells or tissue culture systems has been well established in scientific publications included in this submission. Both products (AIM-V® and DMEM) are manufacturer in accordance with QSR requirements and are labeled as aseptically processed. Thus, AIM-V® Medium is substantially equivalent to the legally marketed device intended for the human *ex vivo* tissue and cell culture processing applications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 23 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kelli L. Tanzella
Manager, Regulatory Affairs
Invitrogen™ Corporation
3175 Staley Road
GRAND ISLAND NY 14072

Re: K022086

Trade/Device Name: AIM-V® Medium

Regulation Number: 21 CFR §876.5885

Regulation Name: Tissue culture media for human ex vivo
tissue and cell culture processing
applications

Regulatory Class: II

Product Code: 78 NDS

Dated: October 14, 2002

Received: October 16, 2002

Dear Ms. Tanzella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

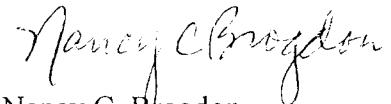
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K022086

Device Name: AIM-V® Medium

Indications for Use:

AIM-V® is a liquid tissue culture media product intended for human *ex vivo* tissue and cell culture processing applications.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K022086

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)